

72 44. (Once amended) A method of making a bioresorbable injectable implant free of materials of animal origin consisting essentially of:

a) providing polymer microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers;

b) providing a gel capable of suspending said microspheres or microparticles, wherein said gel consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant,

c) dispersing said microspheres or microparticles in said gel at a proportion of from about 50 to about 300 grams of microspheres or microparticles per liter of gel;

d) packaging said dispersion into sterilizable, sealable containers; and

e) sterilizing said container.

73 47. (Once amended) A syringe containing a unit dosage form of a bioresorbable injectable implant free of material of animal origin suitable for administration to a human patient in need thereof said implant consisting essentially of:

polymer microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a pharmaceutically acceptable gel capable of suspending said microspheres or microparticles, wherein said gel consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant.

48. (Once amended) A vial containing a unit dosage for of a bioresorbable injectable implant free of materials of animal origin suitable for administration to a human patient in need thereof said implant consisting essentially of:

73
polymer microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a pharmaceutically acceptable gel capable of suspending said microspheres or microparticles, wherein said gel consists essentially of:

water for injection;

from about 0.1 to about 7.5% (wt/wt) of an injectable gelling agent; and

a surfactant.

74
50. (Once Amended) A method of making a freeze-dried material for reconstitution as a bioresorbable injectable implant suitable for administration to a human patient in need thereof consisting essentially of:

providing microparticles or microspheres consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers;

providing a freeze-drying medium consisting essentially of:

a gelling agent free of materials of animal origin,

a cryoprotecting agent,

a surfactant, and

water for injection;

sterilizing said medium;

mixing about 100mg of said microparticles or microspheres with about 1.0 gram of said freeze-drying medium;

homogeneously dispersing said mixture; and

freeze-drying said dispersion.

51. (Once amended) A kit consisting essentially of:

a vial containing an amount of freeze-dried material which upon addition of water for injection is capable of reconstituting a unit dosage of a bioresorbable injectable implant, free of materials of animal origin, suitable for administration to a human patient in need thereof, said freeze-dried material consisting essentially of:

74
microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid copolymers; and

a composition that forms a gel when mixed with water consisting essentially of:

a cryoprotecting agent;

a gelling agent; and

a surfactant;

and an ampule containing a unit dosage of said water for injection.

52 (once amended) A kit consisting essentially of:

a two-compartment syringe wherein:

a first compartment contains an amount of freeze dried material, which upon addition of water for injection is capable of reconstituting a unit dosage of a bioresorbable implant, free of materials of animal origin, suitable for administration to a human patient in need thereof, said freeze-dried material consisting essentially of:

microspheres or microparticles consisting of at least one polymer selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid copolymers; and

a composition that forms a gel when mixed with water consisting essentially of:

a cryoprotecting agent;

a gelling agent; and

a surfactant;

wherein a second compartment contains a unit dosage of said water for injection.

Remarks

Claims 25 to 52 are now in the application. The recent personal interview so courteously granted the undersigned by Primary Examiner Prebilic is hereby noted with appreciation.

I. Support for Amendments

Support for the foregoing amendments to the claims may be found throughout the specification, and in the original claims. Specifically, support can be found at page 6, lines 5-11, of the